M E M O R A N D U M

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

From: Stephanie L. Simek PhD
Deputy Director,
OCTGT/CBER/FDA

To: File STN BL125197

Subject: Teleconference 5/9/07 8:30 AM ET

Liz Smith from Dendreon Corporation called me at 8:30 AM ET/5:30PT to have a brief telecom regarding the Complete Response letter that OCTGT sent to Dendreon the proceeding day, 5/8/07. Attendees on the call from Dendreon were Ms. Smith, Dr. Mark Frohlich, Dr. Nicole Provost and Dr. Mitchell Gold. I was the only CBER person on the call. Ms. Smith started the conversation with concerns they had regarding comments that were in the CR letter. They asked why we had not tried to solve some of the CMC issues earlier since we had been having weekly discussions regarding issues that need clarification. I stated that although a number of the CMC issues may be able to be resolved in a short time period the due date was approaching and the decision was made to not ask for further information so the review process could be finalized and remaining deficiencies were include as comments in the CR letter.

Dr. Gold asked about a meeting between the FDA and Dendreon to discuss outstanding issues cited in the CR letter. Dendreon was informed that OCTGT/CBER would work with them to try and move the process forward. I encouraged Dendreon to submit a request for a meeting and also advised them to submit an agenda on discussion points so OCTGT could be prepared to discuss any issues they had. They stated that they wanted to discuss their ongoing Phase 3 trial 9902B. One concern that was voiced was that the 9902B trial results would not be available until 2010 and they were concerned about the prolonged delay before they could address the deficiencies listed in the CR letter. They wanted to know if it would be possible to discuss with the agency any possiblitiy of coming forward with data earlier than the proposed 2010 date they had projected. . I stated that OCTGT would be open to discussions regarding this issue and that we would be very willing to discuss looking at any data they may obtain earlier than the 2010 projected date.. I also stated that although the FDA was willing to discuss and entertain all available options to move this forward I wanted to make it clear that the FDA in no way wanted to jeopardize the current study because as stated in the CR letter the results

of the ongoing phase 3 study are important to be able to supply the necessary clinical data to support any potential licensure in the future.
I recommended that Dendreon contact Lori Tull the RPM on this BLA and request a meeting. Ms. Smith stated that she was going to call Dr. Peter Bross the clinical team leader for oncology to discuss some safety data information that their safety monitoring board recommended they discuss with the FDA. I informed her that Dr. Bross was available to take her call.

I then asked if it would be possible to discuss what type of information, regarding the FDA action, which Dendreon was going to release to the press. It was at that time that Ms. Smith told me that Dendreon had already put together a press release and had posted it on their website, she said she would send it to me after the T-com. I was told that the press release states that Dendreon received a CR letter and that there were deficiencies in CMC as well as a request for further clinical data.

The last topic that was discussed was brought up by Dr. Gold. He was concerned about what he called “leaks to the press” He wanted to know if there was a chance that the CR letter would be leaked to the press. I assured him that the CR letter is proprietary information and that it would not be released to the press. I also informed him that the FDA would not be actively releasing any press statement. He then asked me if all of the negative press that had been circulating and the letters published in the Cancer letter had any effect on the action that CBER took regarding sending the CR letter instead of approving Sipuluecil-T . He asked if CDER had taken part in the review of the BLA. I told him that the flurry of press regarding their product did not have any effect on the review of their BLA and the final action letter. The resulting action was based on review and analysis of the data submitted in their BLA and the final decision was based on review of that data, and as all of FDA based decisions, was founded on sound science. I also informed Dendreon that CDER did not review any parts of the BLA. I informed Dendreon that CBER and CDER staff routinely attend internal oncology meetings and members of CDER were invited to our internal discussions but were there in a listening capacity and not as reviewers on the BLA.
I again reiterated that the agency will continue to work with Dendreon to help move this forward and the telecom was ended at that time.

Signature_____ Date_____